

## **REMARKS**

### **Status of the Claims**

Claims 1-21, including independent claim 1, are pending in this application. Claim 1 is amended. New claim 22 is added. Reconsideration of the pending claims and consideration of new claim 22 is respectfully requested.

### **Amendments to the Claims**

Claim 1 is amended to recite that “the biasing element has a self-adjusting resistance to allow fluid release at a rate which is proportional to an average pressure difference over time.” Support for the amendment is found in the published application at paragraph [0029] (explaining that “[w]hen CSF force acts on the blocking member 46...the biasing element 50 adjusts according to the pressure exerted on the blocking member 46”). As such, the amendment does not add new matter.

Claim 20 is also amended to depend from claim 19, correcting a typographical error. As such, the amendment does not add new matter.

### **Novelty**

Claims 1-9 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,810,761 to Saens-Arrollo (herein “Saens-Arrollo”). The claims, however, are novel because Saens-Arrollo fails to teach a biasing element in a hydrocephalus valve that has a self-adjusting resistance to allow fluid release at a rate which is proportional to an average pressure difference over time.

Amended independent claim 1 is drawn to a self adjusting hydrocephalus valve for regulating cerebrospinal fluid. The claim recites, *inter alia*, a valve mechanism having a biasing element for exerting a biasing force against the blocking member to selectively maintain the blocking element against the valve seat. In particular, the biasing element “has *self-adjusting resistance* to allow fluid release at a rate which is proportional to an average pressure difference over time.”

Saens-Arrollo provides no teaching or suggestion of a biasing element having a *self-adjusting* resistance. Saens-Arrollo reveals a pressure control device, integrated in a pressure

control valve, for draining cephalorachidian liquid. The patent specifically states that the resistance of the valve “is mainly determined by the [pressure control] device . . . which is *set* to open and close within the *specifically preset* pressure range” (see Saens-Arrollo, column 2, lines 12-15, emphasis added). That is, the resistance of the pressure control device is *predefined* by a *user-chosen* configuration. There is no mention of a biasing element that has an *self-adjusting* resistance as recited in amended claim 1. Accordingly, the Examiner’s observation that Saens-Arrollo reveals “a valve that may be set to open at varying pressures” (see item 6 of the pending Office Action) does not teach or suggest a valve biasing element having a *self-adjusting resistance*. For these reasons alone, amended claim 1 is novel over Saens-Arrollo.

Furthermore, Saens-Arrollo fails to provide any teaching or suggestion of a biasing element “to allow fluid release at a rate which is proportional to an *average* pressure difference over time.” In contradistinction, Saens-Arrollo teaches a valve control device that allows fluid release at a rate proportional to the *instantaneous* pressure difference. As described in Saens-Arrollo, “[t]he flow (F) passing through the equipment is set by the difference in pressure (dP)...and the resistance (R) thereof...The resistance of the equipment is mainly *determined* by the device integrated to the pressure control valve...” (see Saens-Arrollo, column 2, lines 8-15, emphasis added). That is the resistance is *constant*, and therefore the fluid flow is proportional to the *instantaneous* pressure drop. Such a teaching contrasts sharply with the recitation of amended claim 1, in which the fluid release rate is proportional to the average pressure difference over time. Indeed, the recitation of amended claim 1 is not “[a] recitation with respect to the manner in which a claimed apparatus is intended to be employed,” as stated in the Office Action, but a functional limitation of the claim. As discussed in the Manual of Patent Examining Procedure §2173.05(g):

“A functional limitation *must be evaluated and considered, just like any other limitation of the claim*, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step.” (emphasis added)

Thus, the functional limitation provides another basis by which amended claim 1 is novel over Saens-Arrollo.

Accordingly, Saens-Arrollo provides no teaching or suggestion of a biasing element having “a self-adjusting resistance to allow fluid release at a rate which is proportional to an average pressure difference over time.” For these reasons, among other, claim 1 not anticipated by the reference. Claims 2-9 depend from claim 1, and are not anticipated for substantially the same reasons, among others. For example, as discussed in the previous response, claims 6 and 7 are distinguished from Saens-Arrollo since the reference does not teach a valve having an end plate connected to a support member (claim 6), or a support member that includes apertures permitting fluid flow therethrough (claim 7).

Claims 1-9 are clearly novel.

**Nonobviousness**

Claims 10-21 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Saens-Arrollo in view of U.S. Patent No. 5,935,084 to Southworth (herein “Southworth”). The claims, however, are not obvious because, *inter alia*, the references do not teach all the recitations of amended, independent claim 1, from which the claims depend.

As discussed above, Saens-Arrollo does not anticipate amended claim 1 because it fails to teach the recitations of the claim, i.e., a valve mechanism including a biasing element having a self-adjusting resistance to allow fluid release at a rate which is proportional to an average pressure difference over time. Southworth fails to provide the necessary teaching to bridge the gap between Saens-Arrollo and amended claim 1. Southworth provides no teaching of a self-adjusting hydrocephalus valve with a biasing element having a self-adjusting resistance. Indeed, the reference is drawn to a completely different mechanism: a pressure indicator having a fluid-filled bellows for making pressure measurements. There is absolutely no hint, suggestion, or motivation to use the fluid-filled bellows of Southworth to replace the valve control device in Saens-Arrollo whatsoever. Indeed, Southworth teaches away from amended claim 1 by suggesting that shunt systems’ threshold pressures are manipulated by a surgeon who can “initially select a...threshold pressure” (see Southworth, column 1, line 66 to column 2, line 1). That is, the reference only discusses manually adjusted shunt systems. The only way amended claim 1 is achieved is through the teachings of the present application. Thus, the cited art can only render amended claim 1 obvious with the use of impermissible hindsight.

Furthermore, combining the fluid-filled bellows of Southworth with the valve of Saens-Arrollo renders the valve inoperable. As shown in FIGS. 2 and 3 of Saens-Arrollo, the pressure control bellows (C) has perforations (K) to allow fluid to flow through the bellows. If the pressure control bellows is replaced with the fluid-filled bellows of Southworth, the replacement would render the Saens-Arrollo valve unworkable since fluid would not have a passageway to flow through. To puncture the fluid-filled bellows would completely change the operation of the bellows since it is the closed fluid system that provides the pressure response device of Southworth. Only the present application provides the disclosure necessary to combine the elements of Saens-Arrollo and Southworth to practice the pending claims. For example, the subject matter of claim 21, wherein fluid passage does not occur through the biasing element, is supported by the embodiment shown in FIG. 3 of the application and the corresponding discussion at paragraph [0029] of the published application.

Accordingly, the combination of Saens-Arrollo and Southworth cannot render amended claim 1 obvious. Since claims 10-21 also depend from amended claim 1, the claims are also not obvious for at least the same reasons. As such, Saens-Arrollo cannot render claims 10-18 obvious under this rationale. For example, the cited art does not disclose a support member between two bellows (claim 12), and/or a support member including apertures permitting fluid flow therethrough (claim 13). Nor does the cited art teach or suggest a first and second bellows forming a closed fluidic system as recited in claim 14. For all these reasons, and others, claims 10-21 are patentable over the cited art.

It is finally noted that claims 10-18, which depend from claim 1 and include a recitation for two flexible bellows, cannot be “a mere duplication of the working parts of a device found in the prior art,” as stated in the Office Action. for the reasons stated above (i.e., the novelty and nonobviousness of amended claim 1). Contrary to the suggestion in the Office Action that “the second bellows does not appear to cause a different mode of operation,” one embodiment is shown in FIG. 3, and described at paragraph [0029] of the published application, that utilizes changes in volumes of the two bellows to cause the biasing element to act as a damper or shock absorber. As such, the two bellows are not a “mere duplication of working parts.”

**New Claim 22**


New claim 22, dependent from claim 1, is presented for consideration. The claim recites that the biasing element has a damped resistance. Support for the claim is present in the published application at paragraph [0029] (describing a biasing element that acts as a damper). As such, claim 22 is patentable for at least the same reasons that claim 1 is patentable. As well, none of the cited art teaches a valve biasing element that acts as a damper. For at least these reason, the new claim is patentable.

**CONCLUSION**

In view of the remarks above, Applicant submits that claims 1-21 are in condition for allowance, and allowance thereof is respectfully requested. Applicant encourages the Examiner to telephone the undersigned in the event that such communication might expedite prosecution of this matter.

Dated: March 13, 2006

Respectfully submitted,

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